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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,553	02/16/2001	Ming-Ming Zhou	2459-1-003 CIP	3124

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
05/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/784,553	ZHOU ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-36* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 9-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 February 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-6 and 9-36 are pending in the application.

2. In the prior action, the Final action mailed on January 15, 2008, claims 1-6 and 9-36 were pending, with claims 5 and 6 under consideration and rejected; and claims 1-4 and 9-36 withdrawn from consideration.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2008 has been entered.

In the submission, the Applicant amended claim 5.

4. Claims 5 and 6 are under consideration.

Specification

5. **(New Objection)** The specification is objected to for containing referring to sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). See, Figure 1. The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language

> such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d).

It is noted that the Brief summary of Figure 1 indicates wherein the application the sequence identification numbers of the disclosed sequences may be found. However, this is not in conformance with 37 CFR 1.821(d), which requires the use of the sequence identification number in *each* instance where the sequence is provided.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **(New Rejection)** Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claims are drawn to peptides consisting of a sequence consisting of a ZA loop of a bromodomain consisting of the amino acid sequence of SEQ ID NO: 19. However, as indicated in Figure 1, wherein SEQ ID NO: 19 is represented by the hsRing3-1 sequence, SEQ ID NO: 19 comprises more than just the ZA loop. Thus, it is not clear from the claim if the claimed peptide consists of the ZA loop of SEQ ID NO: 19, or consists of the peptide of SEQ ID NO: 19, which includes the ZA loop.

It is noted that claim 6 refers to a peptide sequence consisting of a ZA loop according to SEQ ID NO: 19, wherein the specification identifies the portion of that sequence corresponding to the ZA loop. This claim is therefore not included in the rejection.

For the purposes of this action, the claim is treated as though it reads on peptides consisting of only the ZA loop found in SEQ ID NO: 19 (i.e. residues 25-52 of SEQ ID NO: 19).

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Withdrawn)** Claims 5 and 6 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claim 5 has been amended to remove the functional language of the claim. In view of the amendments to the claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **(New Rejection)** Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Denis et al. (Genes Dev 10:261-71- of record in the action of January 26, 2005) in view of the teachings of Crabtree et al. (US 5,837,840). These claims are drawn to peptides consisting of the ZA loop of SEQ ID NO: 19. SEQ ID NO: 19 is the bromodomain of a protein known a RING3 in the art.

Denis teaches that the RING3 protein is an protein kinase having autophosphorylation activity that is associated with the presence of lymphocytic leukemia. Abstract. The reference teaches that the protein is upregulated in PBLs of patients having with acute and chronic lymphocytic leukemia, but not in normal patients, or in patients in whom the disease has entered remission. Pages 265-267. The reference also teaches antibodies may be used for the detection of the protein, and that anti-RING3 antibodies may be produced through the use of a fusion protein of GST and RING3. Pages 264 and 269. Finally, Denis also discloses an amino acid of the sequence comprising the bromodomain of SEQ ID NO: 19. However, the reference does not teach fragments of the RING3 protein consisting of the ZA loop of a RING3 bromodomain.

Other teachings in the art indicate that immunoassays for proteins associated with lymphocytic leukemia are useful in the diagnosis and staging of the disorder. See e.g., Crabtree, columns 5 and 21. Crabtree indicates in columns 9 and 21 that fragments of the protein may be used to produce and detect antibodies against the protein.

The combined teachings of these references would have rendered obvious the use of fragments of the RING3 protein for the production of antibodies which could be used to detect the levels of the protein expressed in PBL cells for the purpose of diagnosing and monitoring lymphocytic leukemia. It would therefore have been obvious to those of ordinary skill in the art

to have used any fragment of the protein which could be used to raise such antibodies, including the fragment represented by the ZA loop of the bromodomain of SEQ ID NO: 19. The teachings of these references therefore render the claimed peptides obvious.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zachariah Lucas/
Primary Examiner, Art Unit 1648

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CAR §1.821 - §1.825 for the following reasons(s):

[X] 1. This application clearly fails to comply with the requirements of 37 CAR §1.821 - §1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990, and at 55 FR 18230, May 1, 1990.

[ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CAR §1.821(c).

[ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CAR §1.821(e).

[ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CAR §1.822 and/or §1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing".

[ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CAR §1.825(d).

[ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CAR §1.821(e).

[X] 7. Other: See reasons for non-compliance in attached Office action.

APPLICANT MUST PROVIDE:

[ ] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

[ ] An initial or substitute paper copy of the "Sequence Listing", as were as an amendment directing its entry into the specification.

[ ] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CAR §1.821(e) or §1.821(f) or §1.821(g) or §1.825(b) or §1.825(d).

FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE CONTACT:

For Rules Interpretation, call (571)272-0951
Fr Patentin Software help, call (866)217-9197 or (703)-305-3028/308-6845

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE.